DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

m4284m

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John Wolf, President
Contract Pharmacal Corp.
160 Commerce Drive
Hauppauge, NY 11788

October 11, 2000

Ref: NYK-2001-6

Dear Mr. Wolf:

During an inspection of your drug manufacturing facility located at the above address on August 10 through September 1, 2000, our investigator documented deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations include, but are not limited to, the following:

1. You failed to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and drug products as required by 21 CFR 211.110(a). For example, you did not validate the manufacturing process for several of your over-the-counter drug products. These include APAP Film Coated Tablets, Allergy Decongestant Plus Tablets, Benzocaine Capsules, Diphenhydramine HCl Film Coated Tablets, Dologesic Caplets, Ephedrine HCl Tablets, Hangover Helper Tablets, Pyrroxate Cablets, and Spacol T/S Tablets.

2. You failed to justify changes in written specifications as required by 21 CFR 211.160(a). For example, the hardness and/or thickness specifications for several of your over-the-counter drug products were changed as a result of out-of-specification test results. The changes were not justified or validated to determine their impact on the drug products. These include Allergy Decongestant Plus Tablets (lot #092071), APAP Film Coated Tablets (lot #093235), Phenylpropanolamine HCl Timed Tablets (lot #093564), Sinus Tablets Original Formula (lot #094031), and Spacol T/S Tablets (lot #094238).

3. You failed to thoroughly investigate the failure of a batch to meet any of its specifications and to make a record of the investigation including conclusions and follow-up as required by 21 CFR 211.192. For example, your deviation reports for the drug product lots identified in item 2 above, and for drug products lots #001966, #001011, #094034, #092513, #072844, #092276, and #092585, do not thoroughly investigate and document the reasons for the failure to meet product specifications and your follow-up actions.

4. You failed to include complete information in your master production and control records as required by 21 CFR 211.186(b). For example, there were master records that were not specific as to batch size and the weight of each component, nor was there a statement of theoretical weight at appropriate phases of processing or a statement of theoretical yield beyond which investigation is required. Further, there were master records that failed to include complete manufacturing instructions, such as the specific blending and compression equipment and equipment settings to be used.

5. You failed to routinely calibrate, inspect, and check your automatic and mechanical tablet press and encapsulation machines according to a written program designed to assure proper performance and to maintain records of those calibrations and inspections as required by 21 CFR 211.68.

Neither the above identification of CGMP violations nor the inspectional observations (a copy of the Form FDA 483 is enclosed) presented to and discussed with you at the conclusion of the inspection is intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Act and its implementing regulations. The Food and Drug Administration (FDA) advises federal agencies of the issuance of all warning letters about drug products so that they may take this information into account when considering the award of contracts. Additionally, the FDA may not approve pending Antibiotic Form 6, NDA, ANDA, or export approval requests until the above violations are corrected.

You should take prompt action to correct these violations. Your failure to promptly correct these violations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and injunction.

You should notify this office in writing, within 15 working days after receipt of this letter, of (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which the corrections will be completed; (3) any reason why the corrections have not been completed within the response time; and (4) any documentation necessary to show the corrections have been achieved.

Your should send your reply to the attention of Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Tel. (718) 340-7000 ext. 5582.

Sincerely,

Robert L. Hart
Acting District Director

Enclosure: Form FDA 483 dated September 1, 2000